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06/22/2005 02:18 PM

201-15943

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Subject Environmental Defense comments on the  
BQAOH-BQAES Pair

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Environmental Defense appreciates this opportunity to submit comments on the robust  
summary/test plan for the **BQAOH-BQAES Pair**.

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Toxicology and Regulatory Affairs, on behalf of Solutia Inc. and in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted robust summaries and a test plan describing available data for 1,6-bis(dibutylethylammonium)hexane hydroxide (BQAOH, CAS# 111960-92-0) and 1,6-bis(dibutylethylammonium)hexane ethylsulfate, (BQAES, CAS# 68052-49-3) (BQAOH-BQAES Pair).

According to the sponsor this pair of chemicals is produced and used by the sponsor solely at one site (it is not clear from the submission whether there are other producers). All BQAES is converted to BQAOH, which is subsequently used as a process aid in the manufacture of adiponitrile. According to the sponsor, the process is essentially a closed system with minimal occupational exposure or release to the environment. Occupational exposure is said to be limited both by the closed system in which these chemicals are produced and the rigid industrial hygiene precautions necessitated by the acute toxicity of these chemicals.

Our review of the test plan raises some concern regarding the disposal of BQAOH. That is, it is stated in the test plan that, "about half of the BQAOH is burned as part of an organic waste stream and half is released with a wastewater stream to the on-site wastewater treatment plant." It is unclear if this statement refers to the total production volume of BQAOH or that portion of the total that is not consumed through use as a processing aid in the production of adiponitrile, or whether there is a significant difference between these two quantities. It is further stated in the test plan that "BQAOH is not discharged or processed in high enough concentration to interfere with the bacterial flora in the wastewater treatment plant." This statement is presented without supporting evidence and it is unclear whether it refers to interference with the onsite wastewater treatment plant or with any subsequent wastewater treatment plant outside the manufacturing facility that may receive discharge from the onsite plant.

Our review of the test plan and robust summaries indicates that, whereas data to address physical/chemical and environmental SIDS elements for this pair are, while limited, sufficient to meet the SIDS requirements, ecotoxicity and animal toxicity data are insufficient. The test plan proposes to address the SIDS elements required for ecotoxicity with additional testing, but proposes no additional animal studies. The logic for proposing no additional animal testing is based on the limited biological data available and what little is known about the toxicity of these chemicals. Available data indicate that this pair of chemicals is both toxic and corrosive to the skin. Thus, the sponsor reasons that they cannot be humanely or accurately tested in animals. Whereas we do not wish to request unnecessary animal testing, we would point out that the basic principle of toxicology is that *The Dose Makes the Poison*. It follows then that there is some dose, however small, of every chemical that can be studied to determine risks posed by repeated exposure as well as possible adverse effects on development and reproduction. These chemicals could thus be tested for the chronic endpoints at levels below those that cause acute effects.

The sponsor proposes to bridge data from didecyldimethylammonium chloride (DDDMAC) to address those SIDS elements not currently addressed. However, our review of data described for DDDMAC in the test plan and robust summaries indicates that this chemical is much less toxic than the BQAOH-BQAES pair, calling into question use of the former as a surrogate for the pair. We defer to EPA to determine if studies with DDDMAC are sufficient to predict the animal toxicity of the sponsored pair of chemicals.

Note: The studies of DDDMAC described in the robust summaries do actually not name the test substance. The test substance is described as "other TS". We feel it would be more appropriate and more accurate to describe the test substance as didecyldimethylammonium chloride.

In summary, available information for the BQAOH-BQAES pair is limited. This problem will be remedied in part by the proposed studies to address the SIDS elements for ecotoxicity. We believe additional animal studies could be conducted but we defer to EPA to indicate whether they are necessary.

Thank you for this opportunity to comment.

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